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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/740,698	VARNER ET AL.	
	Examiner	Art Unit	
	Bhisma Mehta	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *13 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-129* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68-120 and 129* is/are rejected.

7)☒ Claim(s) *121-128* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 December 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The phrase "that is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a)" should not be used in the declaration and should be replaced with "which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56".

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 1, 26c, 26d, and 26e. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be

notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cap element sized to prevent the cap element from passing through an incision where the cap element abuts the incision or where the cap element mates against the patient eye outer surface must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The abstract of the disclosure is objected to because there is a grammatical error in the first sentence. Correction is required. See MPEP § 608.01(b).

5. Applicant has indicated co-pending applications in the first paragraph of the specification. The first page of the specification should be updated to clarity the status of all related applications noted in the first paragraph of the specification. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Appropriate correction is required.

6. The disclosure is objected to because of the following informalities: There is no brief description of Figure 1a, Figure 4b-1, Figure 4c-1, Figure 4d-1, Figure 4d-2, and Figure 5c.

Appropriate correction is required.

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the cap element being sized to prevent the cap element from passing through an incision where the cap element abuts the incision or where the cap element mates against the patient eye

outer surface. The specification also fails to disclose the body member being in contact with intravitreal fluid.

Claim Objections

8. Claims 108 and 116 are objected to because of the following informalities: Claim 108 recites the limitation "the cap" in line 2. There is insufficient antecedent basis for this limitation in the claim. There appears to be a word missing after "linear" in line 3 of claim 116. There is also a grammatical error in the phrase "the cap element configured to mates against the patient eye" in line 7 of claim 116. Appropriate correction is required.

9. Claims 121-128 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer back to a preceding claim. Claims 121, 122, 126, and 128 cannot refer to claim 129. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 108 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 108, it is unclear if another cap element is being claimed or if the cap element in claim 108 refers to the cap element recited in claim 99.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 68-91, 111-116, and 129 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenman et al (U.S. Patent No. 6,478,776). Rosenman et al disclose an implantable drug delivery device (12) having a non-linear shaped body member with at least two deviations from a linear path and that has a shape other than a substantially C-configuration and that is implanted within a patient to deliver a drug substance to the patient via the body member and a cap element (56) (see Figures 8-19). The cap element is sized such that the cap element is capable of being prevented from passing through an incision through which the device is inserted such that the cap element abuts the incision to stabilize the device. With respect to claims 69-73, see Figures 8-19. With respect to claim 74, the cap element is capable of mating against a patient eye outer surface while the body member is inserted into the eye. With respect to claims 75, the cap element mates the body element at a proximal end of the device. With respect to claim 76, Rosenman et al disclose therapeutic agents for delivery (line 67 of column 3 to line 32 of column 4, line 40 of column 5 to line 10 of column 6, and line 9 of

column 15 to line 35 of column 16). With respect to claims 77 and 78, the body member comprises a polymer and comprises a therapeutic substance that can be delivered to the patient eye (lines 21-36 of column 10 and line 9 of column 15 to line 35 of column 16).

With respect to claims 79, 111, and 129, Rosenman et al disclose an implantable drug delivery device (12) having a coil-shaped body member that is implanted within a patient to deliver a drug substance to the patient via the body member and a cap element (56) (see Figures 4, 5, and 8-19). The cap element is sized such that the cap element is capable of being prevented from passing through an incision though which the device is inserted such that the cap element abuts the incision to stabilize the device. The cap element is in contact with the coil-shaped body member. With respect to claims 80-82 and 112-115, see above.

With respect to claims 83-88, Rosenman et al disclose a method of treating a patient comprising delivering a delivery device comprising a helical, substantially Z-shaped, body member (12) having at least five deviations from a linear path and that has a shape other than a substantially C-configuration and a cap element (56) at a proximal end, inserting into a patient through an incision the device whereby the body member resides in the patient and the cap element remains outside the incision through which the device is inserted and abuts the incision to stabilize the device, and allowing a therapeutic agent to be administered to the patient via the body member. The cap element would be seen to remain outside of and abut the incision as the device of Figure 19 is being inserted through the incision. With respect to claim 89, see lines 15-

35 of column 16. With respect to claims 90 and 91, the body member comprises a polymer and comprises a therapeutic substance that can be delivered to the patient eye (lines 21-36 of column 10 and line 9 of column 15 to line 35 of column 16).

14. Claims 68-91, 111-116, and 129 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman (U.S. Patent No. 5,551,427). Altman discloses an implantable drug delivery device having a non-linear shaped body member (46) with at least two deviations from a linear path and that has a shape other than a substantially C-configuration and that is implanted within a patient to deliver a drug substance to the patient via the body member and a cap element (54) (see Figures 7-11 and line 52 of column 9 to line 67 of column 11). The cap element is sized such that the cap element is capable of being prevented from passing through an incision through which the device is inserted such that the cap element abuts the incision to stabilize the device. The cap element is seen to be capable of mating against the patient eye outer surface when the device is implanted. The cap element as seen in the figures is in contact with the body member at the proximal end (53) of the body member.

With respect to claims 83-91, Altman discloses a method of treating a patient comprising delivering a delivery device comprising a helical, substantially Z-shaped, body member (46) having at least five deviations from a linear path and that has a shape other than a substantially C-configuration and a cap element (54) at a proximal end, inserting into a patient through an incision the device whereby the body member resides in the patient and the cap element remains outside the incision through which the device is inserted and abuts the incision to stabilize the device, and allowing a

therapeutic agent to be administered to the patient via the body member. The cap element would be seen to remain outside of and abut the incision as the device of Figure 7 is being inserted through the incision.

15. Claims 68-71, 74-78, 83-86, 89-91, 99-102, 106-109, and 116-120 are rejected under 35 U.S.C. 102(b) as being anticipated by Weiner et al (U.S. Patent No. 5,466,233). Weiner et al disclose an implantable drug delivery device having a non-linear shaped body member (12) with at least two deviations from a linear path and that has a shape other than a substantially C-configuration and that is implanted within a patient to deliver a drug substance to the patient via the body member and a cap element (16) (see Figure 1). The cap element is sized such that the cap element is capable of being prevented from passing through an incision through which the device is inserted such that the cap element abuts the incision to stabilize the device. With respect to claims 69-71, the device body member comprises at least five deviations from a linear path as seen by the multiple surfaces of the body member. The cap element is seen to be capable of mating against the patient eye outer surface when the body member is inserted into the eye. The cap element mates the body member at a proximal end of the device as seen in Figure 1. The cap element is in contact with the body member. With respect to claim 76, Weiner et al disclose the device comprising a therapeutic agent for delivery to the patient during use of the device (line 33 of column 10 to line 27 of column 11). With respect to claims 77 and 78, Weiner et al disclose the device body comprising a polymer that comprises a therapeutic substance that can be delivered to the patient eye (lines 28-67 of column 8).

With respect to claims 83-86 and 99-102, Weiner et al disclose a method of treating a patient comprising delivering a delivery device comprising a non-linear shaped body member (12) having at least five deviations from a linear path and that has a shape other than a substantially C-configuration and a cap element (16) at a proximal end, inserting into a patient through an incision the device whereby the body member resides in the patient and the cap element remains outside the incision through which the device is inserted and abuts the incision to stabilize the device, and allowing a therapeutic agent to be administered to the patient via the body member. The cap element is seen to remain outside of and abut the incision as seen in Figure 14 where the device of Figure 1 is inserted into a patient eye such that the body member resides in the patient eye. With respect to claim 89, line 33 of column 10 to line 27 of column 11. With respect to claims 90, 91, 106, and 107, the body member comprises a polymer and comprises a therapeutic substance that can be delivered to the patient eye (lines 28-67 of column 8). With respect to claim 108, the cap element mates against the outer surface of the patient eye. With respect to claim 109, the device is inserted by screwing the device into the eye. With respect to claim 117, the incision comprises a sclerotomy. With respect to claim 118, the device is implanted in a minimally invasive surgical procedure. With respect to claims 119 and 120, the device is implanted at the pars plana and the body member is in contact with intravitreal fluid (lines 29-50 of column 5 and line 24 of column 14 to line 5 of column 16).

With respect to claim 116, Weiner et al disclose an implantable ocular drug delivery device having a non-linear shaped body member (12) with at least two

deviations from a linear path and that has a shape other than a substantially C-configuration and that is implanted within a patient eye during use of the device to deliver a drug substance to the patient eye via the body member and a cap element (16) (see Figure 1). The cap element is sized to prevent the cap element from passing through an incision through which the device is inserted and the cap element is configured to mate against the patient eye outer surface while the body member is inserted to the eye.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 72, 73, 79-82, 87, 88, 93-97, 103-105, 111-115, and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner et al in view of Darougar et al (U.S. Patent No. 5,395,618). Weiner et al disclose the implantable drug delivery device substantially as claimed. Even though Weiner et al disclose a non-linear shaped body member, Weiner et al are silent on the specifics of the body member comprising a helical shape or a substantially Z-shape. Darougar et al disclose an implantable drug delivery device having a non-linear body member which comprises a helical shape or a substantially Z-shape as seen in Figures 8 and 12. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the body

member of Weiner et al with a helical shape or a Z-shape as taught by Darougar et al as Darougar et al disclose that it is well known to provide an implantable device with a helical shape or a Z-shape so that the device can be properly positioned and maintained in the desired location in a patient's body.

As to claims 79-82 and 129, Weiner et al disclose the drug delivery device substantially as claimed. However, Weiner et al are silent on the specifics of the body member being coil-shaped. Darougar et al disclose an implantable drug delivery device having a coil-shaped body member as seen in Figures 8 and 12. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the body member of Weiner et al with a coil shape as taught by Darougar et al as Darougar et al disclose that it is well known to provide an implantable device with a coil shape so that the device can be properly positioned and maintained in the desired location in a patient's body.

As to claims 93-97, Weiner et al disclose the method substantially as claimed. However, Weiner et al are silent on the specifics of the body member being coil-shaped. Darougar et al disclose an implantable drug delivery device having a coil-shaped body member as seen in Figures 8 and 12. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the body member of Weiner et al with a coil shape as taught by Darougar et al as Darougar et al disclose that it is well known to provide an implantable device with a coil shape so that the device can be properly positioned and maintained in the desired location in a patient's body.

18. Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman et al in view of Johnson (U.S. Patent No. 5,972,027). Rosenman et al disclose the method substantially as claimed. However, Rosenman et al are silent on the specifics of the device comprising a shape memory material. Johnson discloses an implantable drug delivery device with a non-linear body member that can be made of nitinol, a very well known shape memory alloy of nickel-titanium (lines 39-56 of column 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rosenman et al to make the device of a shape memory material as taught by Johnson as Johnson teaches that it is well known to make an implantable device from a shape memory material to provide a bio-compatible and strong device.

19. Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner et al in view of Darougar et al as applied to claim 93 above, and further in view of Johnson. Weiner et al and Darougar et al disclose the method substantially as claimed. However, Weiner et al and Darougar et al are silent on the specifics of the device comprising a shape memory material. Johnson discloses an implantable drug delivery device with a non-linear body member that can be made of nitinol, a very well known shape memory alloy of nickel-titanium (lines 39-56 of column 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Weiner et al and Darougar et al to make the device of a shape memory material as taught by Johnson as Johnson teaches that it is well known to

make an implantable device from a shape memory material to provide a bio-compatible and strong device.

20. Claim 110 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner et al disclose the method substantially as claimed. However, Weiner et al are silent on the specifics of the device comprising a shape memory material. Johnson discloses an implantable drug delivery device with a non-linear body member that can be made of nitinol, a very well known shape memory alloy of nickel-titanium (lines 39-56 of column 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Weiner et al to make the device of a shape memory material as taught by Johnson as Johnson teaches that it is well known to make an implantable device from a shape memory material to provide a bio-compatible and strong device.

Response to Arguments

21. Applicant's arguments filed June 13 2007 have been fully considered but they are not persuasive. In response to applicant's argument on pages 11 and 12 that Rosenman et al do not teach or suggest a cap element sized to prevent the cap element from passing through the incision where the cap element abuts the incision or mates against the patient eye outer surface, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the

claim. Furthermore, it should be noted that at least while the device as shown in Figure 19 is being inserted through an incision, the body member would be residing in the patient and the cap element would be remaining outside of the incision through with the device is inserted and would abut the incision to stabilize the device or would be capable of mating against the patient eye outer surface.

22. Applicant's arguments with respect to claims 93-97, 99-107, 109, 118, 120, and 129 being rejected under 35 U.S. C. 102(b) over Darougar et al have been considered but are moot in view of the new ground(s) of rejection.

23. Applicant's arguments filed June 13 2007 have been fully considered but they are not persuasive. In response to applicant's argument on pages 13 and 14 that Altman et al do not teach or suggest a cap element that abuts the incision or mates against the patient eye outer surface when the device is inserted, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Furthermore, it should be noted that at least while the device as shown in Figure 7 is being inserted through an incision, the body member would be residing in the patient and the cap element would be remaining outside of the incision through with the device is inserted and would abut the incision to stabilize the device or would be capable of mating against the patient eye outer surface. Also, the cap element of Altman et al is in contact with the proximal end of the body member as seen in Figure 7.

24. Applicant's arguments with respect to claims 68-71, 74-78, 83-86, 90-92, 99-102, 104, 106-110, 116-120, and 129 being rejected under 35 U.S. C. 102(b) over Richter et al have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER